EXHIBIT O-2

'Death Diaries' reveal lessons about prescription drug epidemic

Dr. Roneet Lev wanted to know why San Diegans were overdosing on prescription drugs — and if doctors could turn the deadly trend around.

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JANUARY 6, 2018, 5:30 PM | SAN DIEGO

Quick read

- With the nation in the throes of a prescription drug and opioid epidemic, a doctor in San Diego is helping lead an effort to learn from overdose deaths to prevent future fatalities.
- The "Death Diaries" project examines what drugs killed 254 people in 2013, what they were being prescribed, and by whom.
- Dr. Roneet Lev found several troubling patterns, including doctor shoppers, people mixing drugs with other substances and physicians who don't seem to be paying attention to the prescription drug histories of their patients.

- Hundreds of doctors got a surprise letter in the mail, informing them that one of their recent patients had died from a drug overdose. The letters are part of an experiment to see if doctors change their prescription practices.

Full story

Five days before she died, a 34-year-old woman went to a City Heights Walgreens and filled a prescription for oxycodone.

It was the 54th prescription she had filled in the past year — prescriptions written by 36 different doctors and dispensed by 21 different pharmacies.

The more than 1,300 pills she received in those 12 months top the list of addictive and dangerous prescriptions: opiate painkillers hydrocodone, oxycodone and codeine; sleeping agent Ambien; anti-anxiety med lorazepam; and muscle relaxant carisoprodol, better known as Soma.

This prescription — 24 pills containing 5 milligrams of oxycodone each, a relatively low dosage — would be her last.

On March 11, 2013, she overdosed on the drug.

That year, 253 others in San Diego County shared her fate, dying from unintended prescription overdoses as part of the nation's growing epidemic of pill use and abuse.

But why? The question set Dr. Roneet Lev, the head of emergency medicine at Scripps Mercy Hospital, on a mission to find out. She looked to the dead for answers.

The morbid postmortem examination led her to dub the project the "San Diego Death Diaries," resulting in a body of research that she hopes will save lives and answer one of the troubling central questions in the prescription drug crisis: to what extent is the medical community responsible?

Each "diary" entry is stark in its detail. A name, age and a list of the prescription drugs they overdosed on, followed by a yearlong history of the deceased's medications, the doctors who prescribed them and the pharmacies that filled them. No narratives, no personal background.

But the scant information speaks volumes to Lev. In it are patterns of dangerous drug combinations, of patients mixing substances, of doctor shopping, of well-meaning physicians not paying attention.

"I see these all as preventable," Lev, 54, said in a recent interview at the Hillcrest hospital. "These are people who should be alive."

A realization equally as concerning: More than likely, most of the doctors who prescribed drugs to these overdose victims never knew of their patients' deaths. It has led Lev to the second part of her research: mailing

letters to hundreds of physicians throughout the county informing them that they'd prescribed drugs to someone who'd recently died.

And now she and other researchers are waiting and watching, to see if a letter can change prescribing habits, one doctor at a time.

It took a similar death notification to jolt Dr. Kelly Pfeifer at the California Health Care Foundation in Oakland.

One day she received a call from a coroner informing her that a patient of hers had died, a prescription bottle with Pfeifer's name on it clutched in the dead woman's hand.

"That was a wake-up call," Pfeifer said. "We've got to own our role in this epidemic."

Put on the spot

Not too long ago, prescription opioids like oxycodone were pitched by the drug companies as a safe, non-addictive solution for pain relief — be it chronic back issues to dental surgery recovery to a smashed finger. And many doctors believed it.

The number of prescriptions for these types of drugs grew, and so did access, not only to valid pain patients, but to people addicted to other illicit substances and to teens raiding medicine cabinets.

In response to rising deaths and addiction rates, San Diego County in 2008 created the Oxy Task Force, later renamed the Prescription Drug Task Force, a collaboration of law enforcement, treatment providers, social workers and public officials.

In 2011, the task force invited Dr. Lev and others from the medical community to speak. She — and her profession — were quickly put on the spot. The group demanded to know why doctors were writing all these harmful prescriptions.

She told the audience that doctors were trying their best when patients were in their offices demanding it. "How can you tell people they are not in pain when they are in pain?" she said.

"Usually in the ER I see people angry when I'm not writing prescriptions," Lev recalled. "All of the sudden there's a sea of people really angry about our prescriptions."

Lev came away inspired. She wanted to help turn things around. Which, if you know Lev, isn't surprising.

Born in Israel and raised mostly in Illinois and California, Lev was a junior high student when one of her teachers said girls couldn't be doctors. Lev was determined to prove otherwise.

A classic overachiever, Lev finished high school early and began college at age 16. She went on to medical school at University of Texas at San Antonio and during internships realized her knack for the emerging specialty of

emergency medicine. It matched her personality: high energy, multitasker, the rush of being the first to diagnose.

She ended up at UC San Diego Medical Center in 1990 as one of the first residents in the emergency medicine program there.

She married a Poway dentist and they have four children.

Lev became a leader in the state and San Diego medical community, chairing boards and committees big and small. A glance at her resume makes you wonder how she could possibly take on another project. But she did.

After the task force panel and some unsettling self-reflection, Lev created her own medically-centered task force, which came up with countywide safe prescribing guidelines. It was a start. But there was a certain defensiveness from physicians that kept surfacing.

"'If people just took prescriptions like we told them, then they wouldn't die.' I heard that again and again," Lev said. "Is that true? I have no idea."

Death Diaries

The county Medical Examiner's Office gave Lev the names and toxicology results of all 254 people who had died in 2013 of a prescription drug overdose. She then ran them through the state's prescription database, called the Controlled Substance Utilization Review and Evaluation System, or CURES for short.

In California, pharmacies are required to log into CURES most controlled substances dispensed to a patient, along with the doctor who prescribed it.

Lev found that 186 — or 73 percent — of the overdose victims had filled some kind of prescription in the 12 months leading to their deaths, and she focused on those patients.

"It was a real morbid experience," Lev recalled. "As an ER physician I deal with live patients and keeping people alive. ... I'm going one pharmacy record after the other, 186 of these. All are dead people. It really blew me away."

She found out many of her colleagues were right: 70 percent of the people who died weren't following doctors' orders. But there was more to it than that. She also found red flags that were missed and identified simple ways doctors and pharmacies could have intervened.

The findings

No. 1 drug: The opiate painkiller hydrocodone tied with oxycodone for being connected with the highest number of deaths (48) and accounted for the most prescriptions (990). Most of the pills came from primary care doctors and surgeons.

Deadly cocktails: Most people — 80 percent — who died had a combination of substances in their systems — mixing prescriptions together or with alcohol, over-the-counter medications and illicit drugs.

One of the deadliest combinations was opiates and benzodiazepines. Opiates include oxycodone (OxyContin) or hydrocodone (Norco), while benzodiazepines are a class of anti-anxiety and insomnia medications such as alprazolam (Xanax), lorazepam (Ativan), diazepam (Valium), clonazepam (Klonopin).

The combination was found in 55 — or 21 percent — of the deaths.

What makes the combination dangerous is both types of drugs sedate users and suppress breathing. For abusers, taking both types of drugs together enhances the high. The mixture has long been a concern of doctors, and in 2016 the FDA required both types of drugs to have prominent warnings on bottles.

Ignoring CURES: Doctors are encouraged to check their patients' drug history in the CURES database before dashing off a new prescription, especially drugs prone to abuse. It guards against patients who don't fully disclose their medications and shows when patients shop around for the same prescriptions from multiple doctors.

But there are indications that many doctors aren't regularly using it.

The high number of patients who overdosed on opioids and benzodiazepine combos is a good example, begging the question: Did the various prescribing doctors know of the potential conflict? Was there a missed opportunity to warn their patients about the dangers?

"Most people think CURES is for doctor shopping," Lev said. "It just makes you a better doctor."

"Before giving a prescription that could potentially kill you, take one minute to make sure they don't have that prescription or they're not taking a medication that's going to interact with the prescription," Lev said. "You can't judge people by how they act."

Case in point. Recently, as Lev was working an ER shift, a clean-cut, well-dressed man in good shape came in and asked her to fill a small prescription for Ambien. He said he was leaving the next day on a trip and had trouble sleeping and couldn't reach his primary care physician.

It was a busy day, and it would have been so easy to just write the prescription and move to the next patient, Lev said. But she stopped herself and took the extra minute to look up the man's CURES record.

It was revealing: 17 doctors and 42 prescriptions in the past year. Seventy-five Ambien pills had already been filled that month — by five different doctors.

"After looking at the Death Diaries, I just can't not intervene," she said. "This person could end up in the morgue."

She declined to fill the prescription and counseled him that he appeared to have a problem. He left, not wanting to engage.

But Lev didn't leave it there and sent a note in the CURES messaging system to the 17 doctors on the man's record, alerting them to her concerns. But Lev isn't optimistic the doctors will even see her note. The prescription history indicates most of the doctors probably didn't look at CURES before giving the man Ambien, and there is no way to alert doctors that a message is waiting for them. They have to sign into CURES to see it.

Mystery source: Some people died of drugs they weren't prescribed.

For instance, a glance at the CURES report for a 49-year-old woman wouldn't have raised much concern. She only had 12 prescriptions in the past year — anti-anxiety med clonazepam — prescribed by the same psychiatrist and filled at the same pharmacy.

But when she died March 28, 2013, she had only one drug in her system, oxycodone. No clonazepam.

More than likely, her doctor surmised, she was selling the clonazepam for the oxy, Lev said.

It's why drug screenings can be another useful tool to prescribing doctors, Lev said, to make sure patients are actually taking what they say they are — and to find what else they might be mixing medications with.

Doctor shoppers: Patients who solicit drugs from at least four providers and four pharmacies within the same year are dubbed "doctor shoppers" and have commonly been the face of the prescription drug epidemic. But Lev's study found that only 20 percent of the deceased patients were shopping around for pills.

Those doctor shoppers, however, received half of all the prescriptions written. Another reason why frequent checks of a patient's CURES report could curtail such behavior and give an opportunity for a doctor to intervene, Lev said.

Chronic users: Nearly 70 percent of those who died were being prescribed the same medication for three months or more, making them a chronic user.

"That means if you sprain your ankle or have surgery on a broken leg, fine," Lev explained. "After two months, if you still need that prescription, either the doctor is missing the diagnosis or now you have two problems, you have an addiction and your leg is hurting you."

Chronic users are people who need close monitoring, Lev said. Safe prescribing guidelines calls for the adage "one doctor, one pharmacy" to keep on top of chronic user habits. A medicine agreement is also suggested, a contract of sorts in which the patient admits to understanding the risks and responsibilities with being on a potentially dangerous drug for an extended period.

Methadone: Of the 51 people who died with a single substance in their systems, methadone was the No. 1 killer.

The drug, in the opiate family, is controversial. It is regularly used to treat opioid addiction — keeping users at a baseline operative condition but not getting them high — and is dispensed at clinics or in doctor offices.

But research shows methadone remains a dangerous drug and is one that can be easily abused. It is also considered potentially hazardous to mix with many other drugs, including benzodiazepines, methamphetamine and other opioids.

Also, methadone use is hard for doctors to track via CURES because patients who obtain methadone from clinics are shielded by a privacy law. The source of the methadone that killed many victims in the study remains a mystery, likely a clinic or a provider in Mexico, Lev said.

Another drug being used for "medically assisted treatment" for addicts is saboxone, which is considered safer but still carries some risks.

Lev warns that methadone should be reserved for the most compliant patients and administered with care.

The letters

Lev recognized many of the doctor names she was seeing in the Death Diaries.

"These are my colleagues, good doctors. I trust them," she said. "They have no idea. They don't know what the other one's doing. But I can't tell these doctors they had someone who died. I can only publish the results."

She blamed the inability to inform the doctors of the overdoses on the parameters of the study.

But if she had told them, she wondered if it would change how doctors write prescriptions.

She decided to commission a new study in 2015, got a grant and solicited help from the University of Southern California and Jason Doctor at the school's Leonard D. Schaeffer Center for Health Policy and Economics and Sol Price School of Public Policy.

They obtained the same type of Death Diary data from the medical examiner and CURES for the year 2015. This time, there were 800 total doctors who wrote prescriptions for 248 overdose patients. (Some doctors had multiple deaths, and one had prescribed 10 overdose patients, Lev said. That doctor is no longer practicing, she said.)

They randomly selected 400 doctors from the group and sent them letters notifying them that a patient who they'd prescribed medicine to in the past 10 months had died of an overdose. The language in the letters is not accusatory and instead directs the doctors to a website with safe prescribing guidelines.

The study is tracking the prescribing patterns of those 400 doctors to determine if the letter had any impact, compared to the doctors who were not notified.

Initial results show that the doctors who received letters have been more careful, Lev said. But the study is still ongoing, she added.

If all goes well, she hopes the letters will become standard notification.

Reaction to the letters has been mostly positive, even if it is jarring at first, Lev said.

"It definitely gets your attention," said Dr. Loretta Stenzel, director of adult medical services at Vista Community Clinic. She got a letter about a year ago. It was an overdose victim — a chronic pain patient — whom she had prescribed an opioid to.

"I was covering for another doctor ... who tended to have trouble saying 'no,'" she said. She said she saw the prescription history on the person's CURES report and probably filled it for less to taper him off.

"It does change your prescription pattern," she reflected.

She said she suspects she knows many other doctors who have gotten similar letters from Lev's project, but no one has brought it up. "It might make them uncomfortable, they don't want to talk about it," she said.

Some doctors have been clear they do not appreciate the oversight, complaining about the government watching their prescriptions, Lev said.

Lev's project has gotten national attention. The New York City Department of Health is starting its own letter-notification project, she said.

Lev realizes that she and her colleagues can only do so much to curb this epidemic. The prescription drug problem has spread into the illicit market, hooking users on heroin and counterfeit oxycodone pills that are increasingly being laced with fentanyl, a synthetic opioid that is deadly in the tiniest of doses.

"I have to separate out the supply chain ... As far as the illicit supply, as a doctor I can't do much for that part," Lev said. "As a physician I feel accountable for the Ambiens and the Xanaxes and the oxycodones, and those deaths and that supply chain."

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